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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/177,387	10/23/1998	JAMES L. HARTLEY	0942.2850004	3052

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

34

DATE MAILED: 06/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/177,387

Applicant(s)

HARTLEY ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 100-127 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 100-127 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Receipt is acknowledged of a reply, filed April 3, 2003 as Paper No. 36, to the previous Office Action. Amendments were not made to the claims.

Claims 100-127 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, Paper No. 33, mailed October 3, 2003, that is not addressed in this action has been withdrawn.

Because this Office Action maintains rejections from the previous Office Action and does not raise new grounds of rejection, this Office Action is made FINAL.

### ***Priority***

Applicant's claim for domestic priority to US Provisional Application 60/055,930 under 35 U.S.C. 119(e) is acknowledged and accepted.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 100-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley et al. (WO 96/40724; see entire document; henceforth Hartley) in view of Shuman (US Patent No. 5,766,891). **This rejection is maintained for reasons set forth in the previous Office Action.**

***Response to Arguments Concerning Claim Rejections - 35 USC § 103***

Applicant's arguments filed April 3, 2003, have been fully considered but they are not persuasive. Applicant has argued that the examiner has not established a *prima facie* case as it concerns the rejection of claims 100-127 under 35 USC 103(a) because:

1. There is no motivation to combine the teachings of Shuman and Hartley. Applicant's point out that the fact that some of the sequences recited in the present claims are also present in Hartley is irrelevant because the sequences themselves are not the point of novelty or non-obviousness as it concerns the claimed invention. Applicant further asserts that the Examiner merely points out that it would be "convenient" to combine the disclosure of the cited references, and does not point out a specific motivation from the three permissible sources of motivation.
2. The Examiner is relying strictly on impermissible hindsight to reconstruct the invention by combining the references, again without pointing to some motivation to combine the references to arrive at the claimed invention.
3. The fact that both Hartley and Shuman were known in the art at the time of the invention is not a sufficient finding of obviousness.
4. That there is no such thing as "inherent obviousness", which applicant suggests the Examiner is relying upon in order to combine the Hartley and Shuman references to arrive at the instant invention.

In response to applicant's traversal, the examiner provides the following arguments as to why the rejection is proper:

1. First, the Examiner disagrees that the sequences themselves are of no particular relevance to the claimed method. In fact, it appears that the sequences that are used in the primers are indeed the basis for the novelty of the method. These sequences must not contain stop codons, must not contain sequences that contribute to hairpin formation, must be selected from SEQ ID NO: 1-16 or a sequence 80-99% identical thereto, or must be 80-99% identical to SEQ ID NO: 39-43. If these limitations were not in place, then the method would be entirely different, essentially reading on PCR technology.

Second, the Examiner does not merely state that it would be “convenient” to combine the references as “motivation” to combine the references. Rather, the Examiner indicates that it would have been *obvious* to combine the teachings because Hartley teaches a method of cloning using particular sequences, wherein these sequences can be in the form of PCR products (see for example page 30, lines 20-22 and lines 27-28), and the teachings of Shuman are convenient for modifying sequences to contain specific elements that are useful for cloning, wherein the sequences are added to primers for use in generating PCR products (see for example column 7, lines 13-23). Thus, the “convenience” is not relevant to the combination of the references, but rather to the nature of the method described by Shuman.

The Hartley reference concerns improving the efficiency of cloning techniques (see for example page 4, lines 18-26), wherein the nucleic acids used in the cloning techniques comprise sequences that fit the limitations of the instant claims (see for example page 26, line 16 to page 27, line 7 and page 29, line 29, line 4 to page 30, line 15) and can be in the form of PCR products (see for example page 30, lines 20-22 and lines 27-28). Hartley does not explicitly teach using their particular sequences in primers to obtain a duplex PCR molecule with the recombination

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sites present at the ends of the molecule. However, it is clear that, if a PCR molecule could be used in the method, than a PCR molecule must be generated. Shuman clearly teaches a convenient, general method for the generation of a PCR molecule comprising specific sequences, wherein the specific sequences can be introduced via primers used in a PCR reaction. It would be obvious to the ordinary skilled artisan that adding the recombination sequences of Hartley to primers, as opposed to the topoisomerase sequences, as taught by Shuman, would result in the generation of a PCR product that can be used in the method of Hartley, as is suggested by Hartley. Thus the combination of the references would be obvious to one of ordinary skill in the art. Motivation to combine these references comes from providing a more efficient method of cloning, which is clearly the point of Hartley (see for example page 6, lines 18-26).

Finally, the motivation and obviousness provided in the previous Office Action, and as reiterated and clarified above, does indeed come from the teachings of the prior art, specifically those references that are applied, as evidenced by the specific teachings in both the Hartley and the Shuman references.

2. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

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3. As it is clearly stated above, there was clear obviousness and motivation to combine the Hartley and Shuman references. Although it was necessary that both teachings were known in the art at the time of the invention, the Examiner does not rely solely on this fact in order to assert the rejection. The obviousness comes from a need to generate the PCR product to be used in the method of Hartley, and the teachings of Shuman on how to, in general, produce a duplex PCR molecule with a desired sequence by placing the sequence in a primer. Motivation comes from Hartley, where it is desirable to produce an efficient method of cloning. Therefore, applicant's assertion that the Examiner has relied solely on the existence of the two references is unfounded.

4. Applicant argues that there is no such thing as "inherent obviousness," upon which it is asserted that the Examiner is basing the rejection of the claims. It is important to note that the Examiner in no way suggests that the obviousness or motivation to combine the teachings is inherent. Rather, the Examiner asserts that the properties of the sequences disclosed by Hartley are inherent in that the sequences are mutated *att* sites, wherein the mutations remove the existence of stop codons, etc. In fact, upon closer inspection of the Hartley reference, these properties are not inherent, but are explicitly disclosed. Therefore, applicant's argument that there is no such thing as "inherent obviousness" is moot both in light of the fact that the obviousness of combining the references is not claimed to be inherent and because the properties which the Examiner asserted were inherent were actually explicitly taught by the reference.

In conclusion, applicant's arguments concerning the rejection of claims 100-127 under 35 USC 103(a) are not persuasive for the purpose of traversing the rejection. The Examiner has clearly established a *prima facie* case of obviousness, showing both a motivation and an

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obviousness to combine the Hartley and Shuman references. None of the arguments presented by applicant questioned that the teachings themselves did not address the claimed invention, therefore the rejection is still deemed proper and is maintained.

***Allowable Subject Matter***

No claims are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8 am to 4:30 pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson  
June 6, 2003

DAVID GUZO  
PRIMARY EXAMINER  
